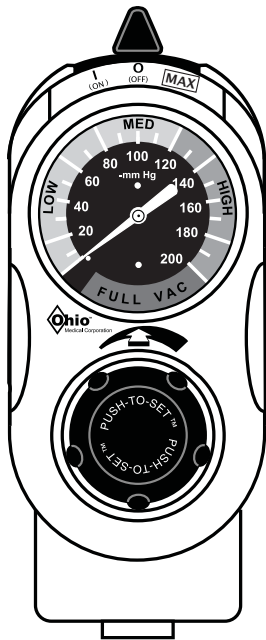


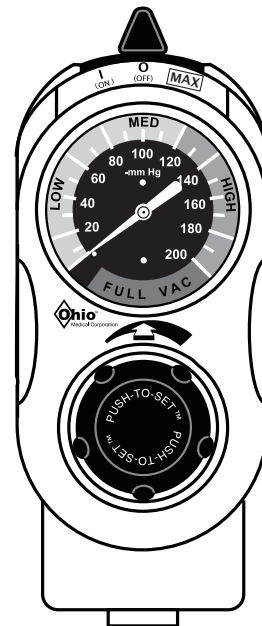
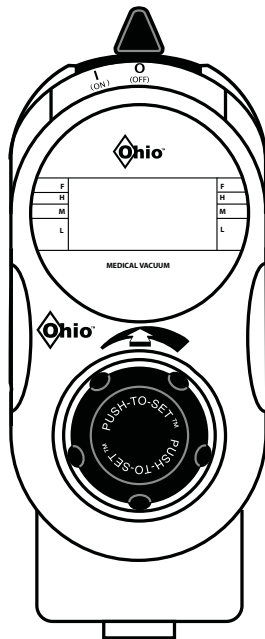
Push-To-Set™

Continuous Vacuum Regulators (PTS-CVR)

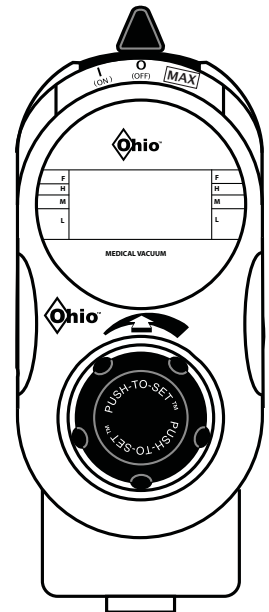
Service Manual



2 Mode



3 Mode



User Responsibility

IMPORTANT: Federal law in the U.S.A. and Canada restricts this device for sale by or on the order of a license medical practitioner.



WARNING: This device is to be used only by persons who have been adequately instructed in its use.



WARNING: Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained

and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, see the Ohio Medical service manual for service or repairs to this product. For service advice, Ohio Medical recommends that a telephone request be made to the nearest Ohio Medical Regional Service Center. This product or any of its parts should not be repaired other than in accordance with written instructions provided by Ohio Medical or by Ohio Medical trained personnel. The Product must not be altered without the prior written approval of Ohio Medical's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Ohio Medical.

Product Date Coding:

AAAA 12345



This alpha character indicates the year of product manufacture and when the serial number was assigned; "L" = 2007, "M" = 2008, "N" = 2009, etc. "I" and "O" are not used.

Technical Competence

The procedures described in this service manual should be performed by competent individuals who have a general knowledge of and experience with devices of this nature. No repairs should ever be undertaken or attempted by anyone not having such qualifications.

Genuine replacement parts manufactured or sold by Ohio Medical must be used for all repairs.

Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure.

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1/Precautions

Definitions

Note: A Note provides additional information to clarify a point in the text.

Important: An Important statement is similar to a note but of greater emphasis.

-  **CAUTION:** A CAUTION statement is used when the possibility of damage to the equipment exists.
-  **WARNING:** A WARNING statement is used when the possibility of injury to the patient or the operator exists.

MAX	= maximum
High Flow High Vacuum	= high flow, high vacuum
High Flow Low Vacuum	= high flow, low vacuum
I (On)	= on
O (Off)	= off

Abbreviations Used In This Manual

CCW	Counterclockwise (Anti-clockwise)
CVR	Continuous Vacuum Regulator
MAX	Full Line Vacuum
in Hg	Inches of mercury
kPa	Kilo pascals (kPa x 7.50 = mm Hg)
LPM	Liters per minute
mm Hg	Millimeters of mercury (mm Hg x .133 = kPa)
°C	Degrees Celsius
°F	Degrees Fahrenheit
N-m	Newton-Meter (N-m x .737 = ft-lb)
ft-lb	Foot-Pound Force (ft-lb x 1.356 = N-m)
oz	Ounces
DISS	Diameter Index Safety System
OES	Oxequip Suction
NCG	National Compressed Gases (Chemetron)
NPT	National Pipe Thread (USA)
NPTF	National Pipe Thread Female (USA)
MPTS	Multi-Purpose Therapy Stand
gal	Gallon
PTFE	Teflon®
PTS	Push-To-Set™

1.2 Warnings

After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.

Clean and sterilize all suction equipment before shipment or service to ensure transportation personnel and/or service personnel are not exposed to any hazardous contamination.

Connect the Vacuum Regulator to the vacuum source only and check its operation before attaching the patient connection. Connection to pressure sources even momentarily could injure the patient or operator and damage the equipment.

Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.

If the Vacuum regulator is repaired or disassembled in any manner, the Service Checkout Procedure must be performed before using the equipment on a patient.

1.3 Cautions

Do not lubricate any internal components of the regulator module.

Do not use any Loctite® products to seal the fitting and adapter port threads (or products which contain Methacrylate Ester as an active ingredient).

Only competent individuals trained in the repair of this equipment should attempt to service it.

To help prevent aspirate from entering the regulator, as a result of misuse, an Overflow Safety Trap and suction filter should be attached prior to its use. Aspirate in the regulator will impair the operation. The use of the Overflow Safety Trap and suction filter will help prevent this and extend the life of the suction equipment.

Use of lubricants other than recommended may degrade plastic or rubber components.

Prior to placing the unit back into service after repair or disassembly, perform the Service Check-out Procedure.

Not for Field or Transport use**

®Loctite is a registered trademark of the Loctite Corp.

** The categories of Field and Transport Use are specifically defined in ISO 10079-3. "Field" means use at accidents or emergencies outside a hospital. "Transport" means use in ambulances, cars and airplanes. These situations may expose the equipment to uneven support, water, dirt mechanical shock and temperature extremes. Ohio Medical suction equipment has not been tested to comply with the specific requirements of these categories.

This service manual contains service, maintenance and parts information on all models of the Push-To-Set™ Continuous Vacuum Regulator.

North American

International

2.1 North American (ANSI) Vacuum Regulators

Note: Part numbers given are for PTS-CVR without fittings or adapters.

3/Specifications

3.1 Description

⚠ WARNING Do not use this device in the presence of flammable anesthetics. Static charges may not dissipate and a possible explosion hazard exists in the presence of these agents.

The PTS-CVR is a lightweight, compact unit used throughout the hospital primarily for pharyngeal/tracheal suctioning (airway management). Various models provide regulated or full-line vacuum for hospital suction procedures.

There are several models of the PTS-CVR. All models contain a vacuum gauge which indicates suction supplied by the regulator. Each has a positive pressure safety relief valve to prevent pressurization by either failed injector vacuum (venturi) units or inadvertent cross connection to pressurized gasses. In addition, the Low PTS-CVR models include a vacuum relief valve to limit maximum suction.

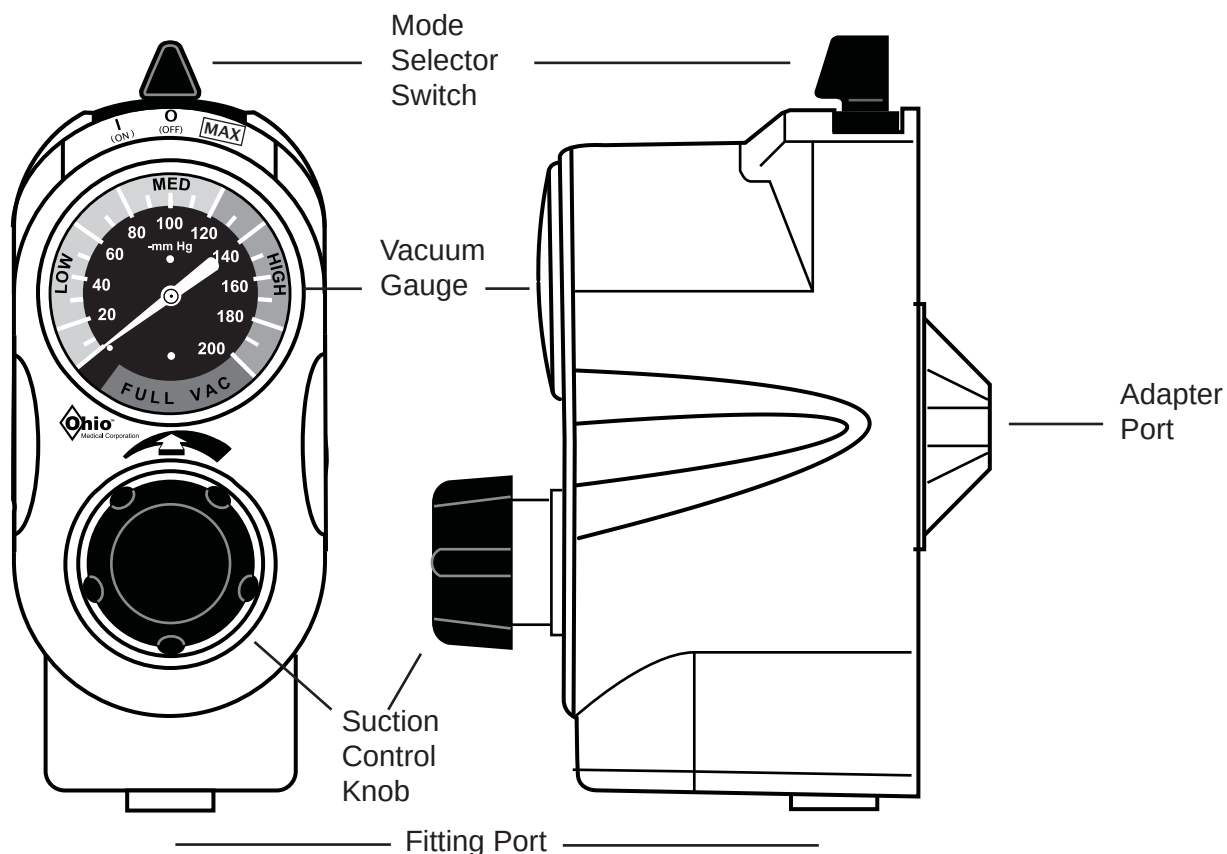
Some models operate in a regulated or non-regulated (MAX) mode. Others operate only in the regulated (limited) mode.

In the non-regulated (MAX) mode, the vacuum source is connected directly to the fitting port. The regulator module is bypassed and full-line vacuum is provided.

In the regulated (limited) mode, the vacuum source is connected through the regulator module which functions as an automatic valve. Turning the suction control knob adjusts the position of the regulator module and allows selection of a predetermined level of suction when set according to instructions.

During use, as the flow requirement increases, the valve automatically opens to maintain suction at the preset level. Conversely, when the flow requirement decreases, the valve automatically closes to maintain suction at the preset level. The same mechanism compensates for changes in supply vacuum and automatically maintains the pre-set suction level when set according to instructions.

1. Suction Control Knob - Allows easy adjustment of suction to the patient.
2. Mode Selector Switch - Allows quick and easy mode changes.
 - a. | (On) - Suction can be adjusted with the suction control knob.
 - b. O (Off) - No suction is supplied to the patient.
 - c. MAX - Maximum full-line vacuum is supplied to the patient.
3. Vacuum Gauge - The suction level to the patient is displayed during use.



3.2 Specifications

Gauge:	Accuracy(Analog): ±5% of full scale deflection Accuracy(Digital): ±1% of full range at 22°C
Flow Rate:	0 to 80 LPM without fittings at full increase setting depending on supply vacuum and open air flow
Positive Pressure Safety Relief Valve:	Located in the vacuum supply line to prevent pressurization of the patient connection by failed injector vacuum (venturi) units, or inadvertent cross connection to pressurized gases
Ranges:	Gauge Range Regulated Suction
Standard Models	0 to 200 mm Hg/0 to 26 kPa 0 to 760 mm Hg/0 to 100 kPa
High Models	0 to 760 mm Hg/0 to 100 kPa 0 to 760 mm Hg/0 to 100 kPa
Low Models	0 to 160 mm Hg/0 to 21 kPa 0 to 135 mm Hg/0 to 18 kPa*
* When measured with an independent measuring device.	
Vacuum Relief Valve (Low Vacuum models ONLY):	140 mm Hg ± 5 mm Hg/18.7 kPa ± 0.7 kPa
Weight: (Less fittings)	11 oz/312 grams
Weight Low Vacuum models: (Less fittings)	12 oz/340 grams
Dimensions: (Less fittings)	Height: 5.7 inches/145 mm Width: 3.0 inches/76 mm Depth: 3.8 inches/96 mm
Latex tubing, 0.25 in (6.4 mm) I.D. X 12 in (30 cm) supplied:	0 to full vacuum Flow dependent on source and setup
Disposable tubing (Available separate in some markets; 6 mm I.D. X 450 mm, 750 mm and 2M) to connect regulator and collection bottle	0 to full vacuum Flow dependent on source and setup
Disposable Suction Filter:	0 to full vacuum 0 to 100 Lpm @ 650 mmHg (-87 kPa)
Environmental Specifications	
Operating Temperature Range:	40°F (4°C) to 120°F (49°C)
Storage Temperature Range:	0°F (-18°C) to 150°F (71°C)
Operating and Storage Relative Humidity:	5 to 95%

4/Operation

4.1 Equipment Set-up

Insert the probe into the vacuum wall outlet. If the regulator is mounted elsewhere, connect a vacuum supply hose between the regulator's probe adapter and the wall outlet.

⚠ WARNING Connect the vacuum regulator to the vacuum source only and check its operation before attaching the patient connection. Connection to pressure sources, even momentarily, could injure the patient or operator and damage the equipment.

Note: For proper installation of Adapters/Probes and Fittings see Appendix.

Connect the collection bottle's vacuum port to the regulator's fitting port or Overflow Safety Trap with the appropriate suction filter and vacuum tubing.

An Ohio Medical High Flow Suction Filter should be used between the collection container and regulator to prevent contamination of the regulator.

Use hospital-supplied suction tubing between the end piece and the collection container, and between the patient port and the patient (minimum inside diameter is 6 mm [0.25 in.]).

ISO 10079-3 (BS 7259: Part 2, section 5.1.2) states that "the usable volume of the collection container shall not be less than 500 ml."

Suction Filters

Hydrophilic:

Nipple

Pkg of 20	6730-0350-800
Pkg of 200	6730-0351-800

Hydrophobic:

Nipple

Threaded

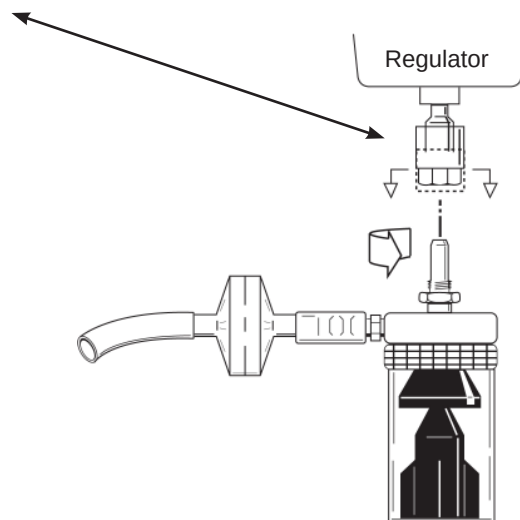
Pkg of 3	6730-0570-800	6730-0580-800
Pkg of 10	6730-0571-800	6730-0581-800
Pkg of 100	6730-0572-900	6730-0582-800

4.2 Attaching the Overflow Protection Device (OPD)

⚠ CAUTION: To help prevent aspirate from entering the regulator, wall outlet and pipeline system as a result of misuse, an Overflow Safety Trap should be attached prior to its use. Aspirate in the regulator, wall outlet and pipeline system may impair their operation. The use of the Overflow Safety Trap and suction filter will help prevent this and extend the life of suction equipment.

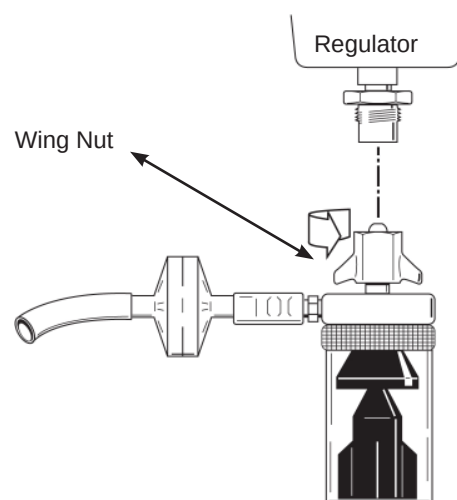
Locking Gland Fitting

1. Raise the sleeve and insert the trap into the regulator fitting.
2. Turn the trap clockwise about one and a half turns to engage the threads. The trap does not need to be screwed tight; an O-ring in the regulator fitting provides a vacuum seal. The trap should rotate freely to allow the desired tubing positioning.
3. Lower sleeve to lock trap in position.



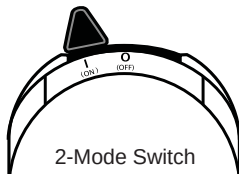
DISS fitting

1. Insert trap into the regulator fitting. Situate the tubing in the desired position.
2. Turn the DISS wing nut clockwise to engage threads and tighten (there is no O-ring, so the vacuum seal depends on a tight connection).

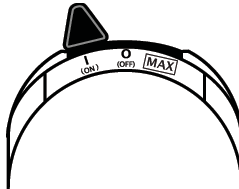


4.3 Mode Selection

I (On) - Suction can be adjusted with the suction control knob.

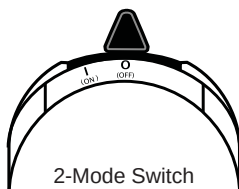


2-Mode Switch

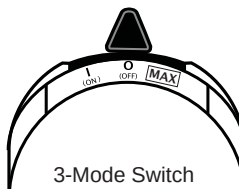


3-Mode Switch

O (Off) - No suction is supplied to the patient.

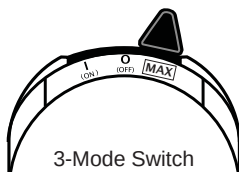


2-Mode Switch



3-Mode Switch

MAX - Maximum, full-line vacuum is supplied to the patient.



3-Mode Switch

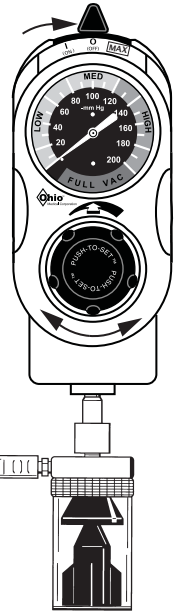
Note: available on three mode vacuum regulators only.

4.4 Setting the Suction Level

1. Turn the mode selector switch to I (On).
2. Occlude or clamp tubing
3. Rotate the suction control knob until the vacuum gauge indicates the required setting.



WARNING The regulator fitting port or patient connector must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.



4.5 Pre-Use Checkout Procedure



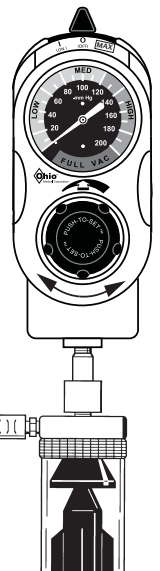
WARNINGS: The Pre-Use Checkout Procedure must be performed before using the equipment on each patient. If the regulator fails any part of the Pre-Use Checkout Procedure, it must be removed from service and repaired by qualified service personnel.



WARNINGS: Connect the vacuum regulator to the vacuum source only and check it's operation before attaching the patient connection. Connection to pressure sources, even momentarily, could injure the patient or operator and damage the equipment.

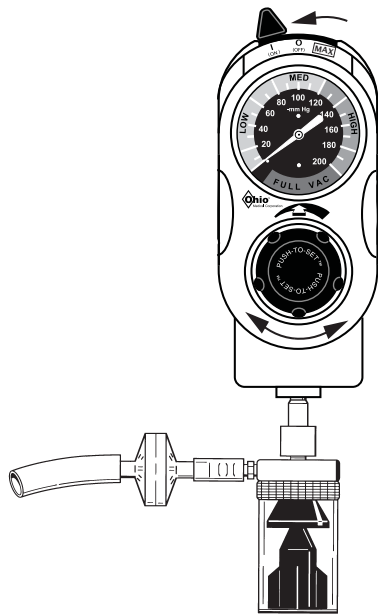
All tests must be performed with supply vacuum of 380 mm Hg (51 kPa) minimum.

1. Turn the mode selector switch to O (Off). Rotate the suction control knob one full turn clockwise (increase). Clamp tubing to occlude the fitting port. The gauge needle should not move.
2. Turn the mode selector switch to I (On). Rotate the suction control knob fully anti-clockwise (decrease). Clamp tubing. The gauge needle should not move.



4/Operation

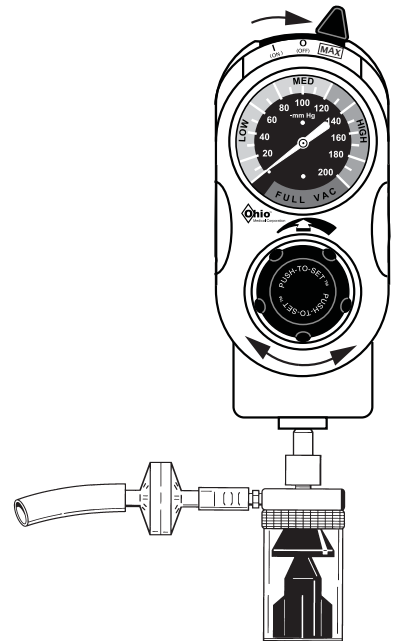
3. Clamp tubing.



Turn the mode selector to MAX. Clamp tubing and check that the gauge needle indicates the maximum available suction.

Turn the mode selector to I (On).

- 4b. Low Continuous
Clamp tubing and rotate knob fully clockwise (increase) to verify the suction level does not exceed 150 mm Hg (20 kPa).



4. Regulator Setting

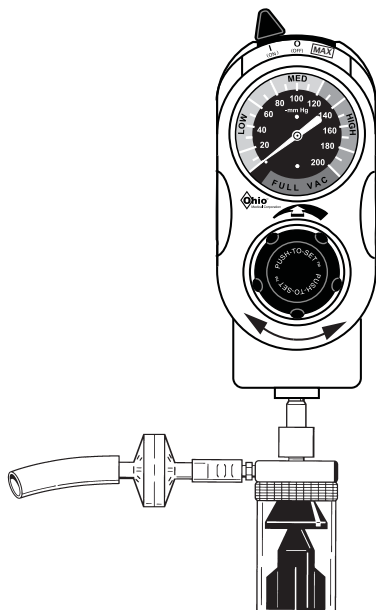
Standard & Low: increase the suction to 100 mm Hg (13 kPa)

High: increase the suction to 300 mm Hg (40 kPa)

Slowly open and close the clamped tubing to create various flow rates through the regulator. Check that the suction level is maintained when the tubing is clamped.

For Standard 2 Mode Continuous, go to step 5.

4a. High and Standard 3 Mode Continuous

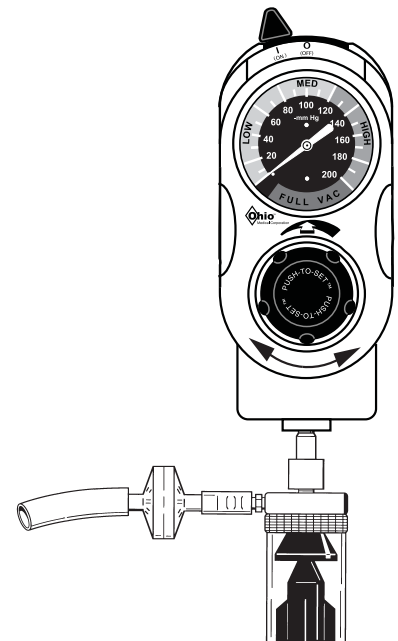


Pre-Use Checkout



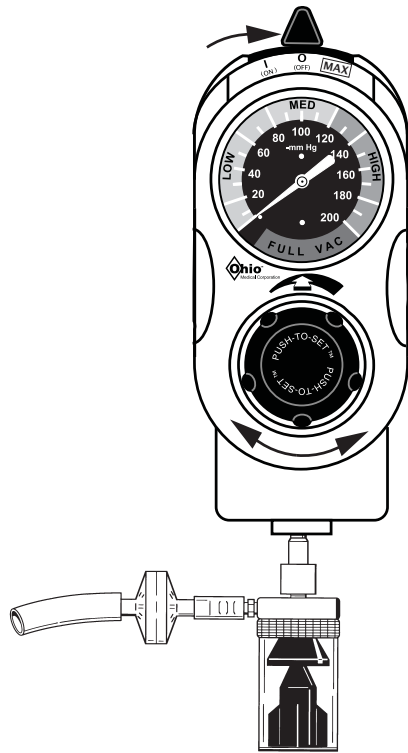
WARNING: Test performed at ≥ 500 mmHg (67 kPa)

1. Reduce the suction level to zero and set the mode selector switch to O (Off).

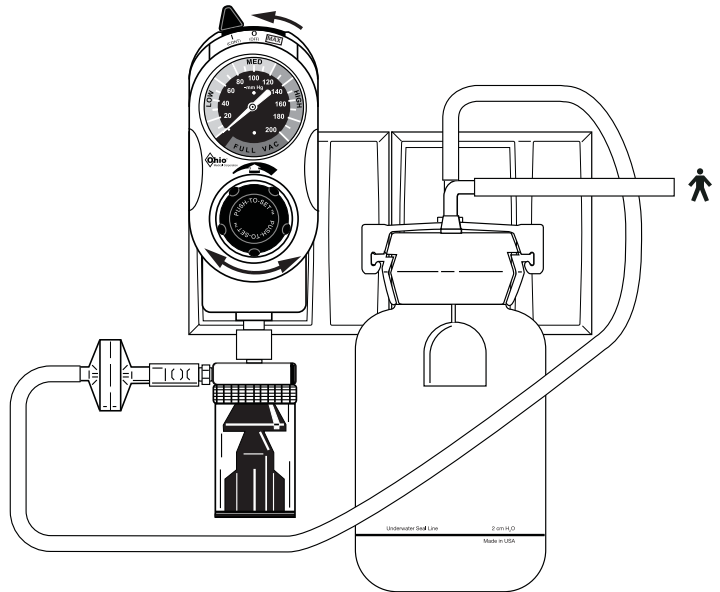


4.6 Patient Setup

1. Make sure the Pre-Use Checkout Procedure has been performed.



4. Turn the mode selector switch to O (Off).
5. Attach tubing to the vacuum port of the collection container.

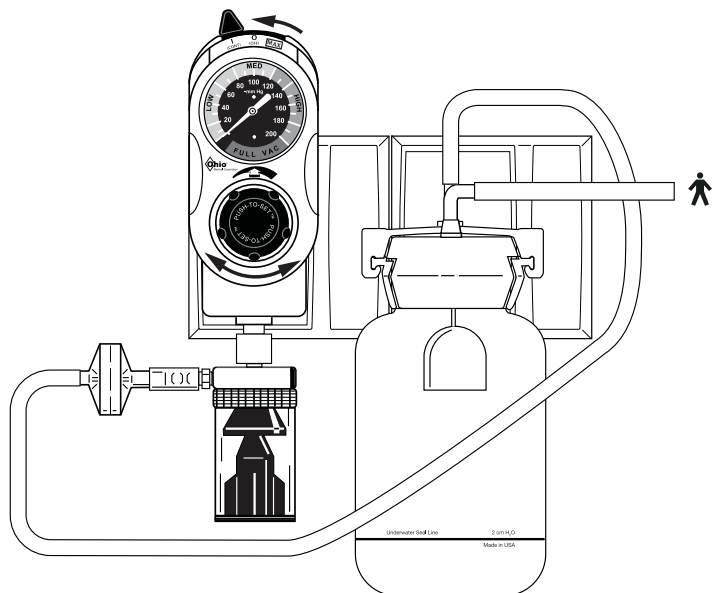
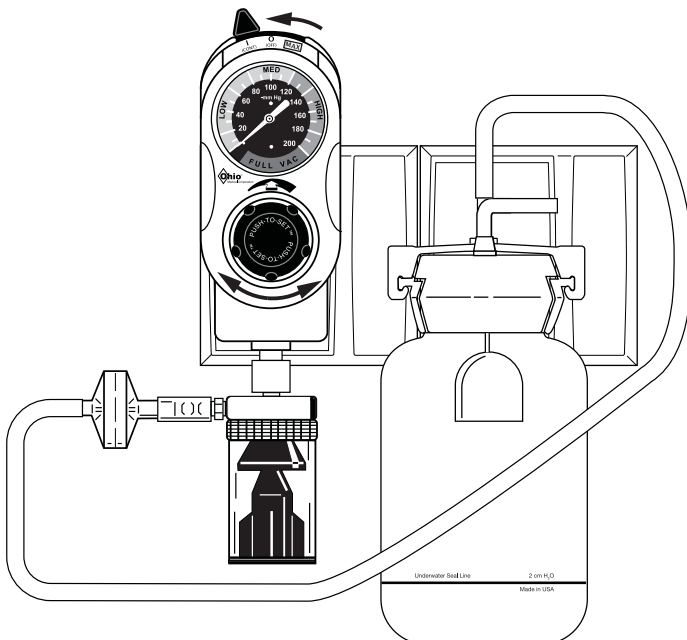


2. Turn the mode selector switch to I (On) and use PTS
3. Set the prescribed suction level.



CAUTION: The PTS must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.

6. Turn the mode selector switch to I (On). Important: The Low models do not deliver suction in excess of 150 mm Hg (20 kPa).



5/Cleaning & Sterilization

5.1 Cleaning



WARNING: After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.

5.1.1 Routine Exterior Cleaning

Routine cleaning of the regulator is recommended as a standard procedure after each use.

Wipe all exterior surfaces with a solution of water and mild detergent.

5.1.2 Internal Component Cleaning



CAUTION: Cleaning the gauge may result in damage.

The regulator requires cleaning if it becomes flooded with patient fluid as a result of misuse.

1. Refer to the Service - Disassembly and Assembly instructions.
2. All internal components, with the exception of the gauge, may be cleaned with a solution of warm water and mild detergent.
3. Dry all components with a lint free cloth before assembly. Dry internal passages using vac flow or compressed air.

5.1.3 Cold Flush Procedure



CAUTION: Do not cold flush digital unit

If desired, the vacuum regulator can be cold-flushed as part of a cleaning or disinfecting procedure. Set up a collection canister or liner between the vacuum source and the adapter/probe port of the vacuum regulator to receive the flush solution. Suction through the vacuum regulator an adequate amount of cold disinfectant to satisfy the infection control requirements of the hospital. Use only approved cleaning/flushing solutions. Make sure those made from concentrates are newly mixed to ensure effectiveness.

Flush both the continuous and intermittent vacuum circuits thoroughly. Adequately aerate both the continuous and intermittent circuits with vacuum flow or compressed air until all internal channels, switches, gauge ports and regulating mechanisms are dry. Disassemble to check O-rings for adequate lubricant and filters for proper function following any cold flush procedure. Perform Service Checkout Procedure (Section 8).

5.1.4 Disinfection

Should misuse occur resulting in accidental flooding of the regulator, the regulator may be disinfected using Ethylene Oxide (ETO). After disinfection, follow the service checkout procedures in Section 8.



WARNING: Following disinfection with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Follow ETO processor's recommendation for specific aeration periods required.



CAUTION: Do not steam autoclave or liquid sterilize the PTS-ISU. Severe impairment to the operation of the regulator will result.



CAUTION: Disinfection with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts.

Note: The PTS-ISU should only be disinfected if it is contaminated or maintenance is to be performed.

1. The regulator should be disinfected with the mode selector switch in the |O|O (INT) position.
2. Ethylene oxide mixtures can be used at temperatures of 125 to 135°F (52-57°C). If this temperature cannot be obtained, room temperature sterilization with 100% ethylene oxide can also be used. Disinfection is NOT recommended as a frequent procedure.
3. After each disinfection check the condition of the internal filters. Replace any shrunken filters before returning the regulator to service.
4. Perform Service Checkout Procedure (Section 8).

5.2 Sterilization

Should misuse occur, resulting in accidental flooding of the regulator, the regulator may be sterilized using Ethylene Oxide (ETO). After sterilization, follow the service checkout procedures in Section 8.



WARNING: Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 130°F (54°C).



CAUTION: Do not steam autoclave or liquid sterilize the Continuous Vacuum Regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).



CAUTION: Sterilization with ethylene oxide mixtures may cause crazing (minute superficial cracking) of some plastic parts. Crazing will be more pronounced when mixtures containing Freon® are used.

Place the regulator in the vertical position and connect to a supply vacuum of 500 mm Hg + 10 mm Hg (67 kPa + 1.3 kPa)

Note: The Vacuum Regulator should only be sterilized if it is contaminated or maintenance is to be performed.

1. The regulator should be sterilized with the mode selector switch in the | (On) position.
2. The only acceptable method of sterilization is with ethylene oxide. Ethylene oxide mixtures can be used at temperatures of 125 to 135 °F (52 - 57 °C). If this temperature cannot be obtained, room temperature sterilization with 100% ethylene oxide can also be used. Sterilization is not recommended as a standard procedure after each use.
3. After each sterilization, check the condition of the internal filter. If the filter appears to have shrunk, replace it before placing the regulator back in service.
4. Adequately aerate the regulator prior to disassembly, shipment or use. Aerate parts prior to reassembly.

®Freon is a registered trademark of the DuPont Company.

6/Troubleshooting

Problem	Possible Causes	Remedy
A. No gauge indication and no suction in any setting	1. No supply vacuum 2. Kinked tube 3. Poor connection 4. Blocked wall outlet 5. Blocked adapter/probe port 6. Blocked backplate 7. Blocked adapter	1. Correct supply problems 2. Straighten tube 3. Check all connections and seals 4. Unblock outlet 5. Unblock port 6. Clean with soap and water and a pipe cleaner 7. See "regulator module malfunction" under the Problem column in this section of the manual
B. Regulator module malfunction	1. O-ring, quad ring, or diaphragm failure 2. Cap not completely snapped to housing 3. Springs are not installed correctly 4. Pinched diaphragm	1. Replace rubber components 2. Fully snap cap onto housing 3. Ensure that springs are properly installed. 4. Reinstall or replace diaphragm
C. No gauge indication but suction is being delivered	1. Blocked gauge pressure sensing orifice 2. Blocked gauge pathway (through Unilogic Module) 3. Failed gauge o-ring seal 4. Gauge mechanism is damaged 5. Dead Batteries*	1. Unblock orifice 2. Clear pathway 3. Reinstall or replace the o-ring 4. Replace gauge 5. Replace Batteries*
D. Gauge indication but no suction is being delivered	1. Knob fails to return when pushed 2. Blocked fitting port 3. Overflow Protection Device Shut-off 4. Blocked external suction filter 5. Blocked fitting 6. Leak in system	1. Remedy: i. Jiggle knob ii. Verify actuator is installed properly iii. Replace worn drive gear iv. Replace cover if worn splines in well v. Replace Push-To-Set™ assembly 2. Unblock port 3. Reset float, empty and disinfect the Overflow Protection Device 4. Replace external filter 5. Clean or Replace fitting 6. Remedy: i. Check lid is secure on the collection container ii. Check tubing connections
E. Suction level cannot be adjusted	1. Failure to push knob and rotate 2. Regulator module is stuck in full OFF or full ON position 3. Regulator module malfunction	1. Push and rotate to set vacuum level 2. Push and rotate knob counterclockwise to un-stick 3. See "Regulator module malfunction" under the Problem column in this section of the manual
F. Suction level can be adjusted without pushing the knob in	1. Worn or broken drive gear 2. Worn or broken splines in well 3. Broken knob	1. Replace drive gear 2. Replace cover 3. Replace knob

*Digital Unit Only

Problem	Possible Causes	Remedy
G. Insufficient flow through regulator	1. Partial blockage in wall supply 2. Partial blockage in regulator 3. Push-to-Set™ spring assembly does not return, blocking the flow path 4. Knob fails to return when pushed 5. Vacuum relief plug leaks or is missing 6. Positive pressure relief valve leaks or is missing	1. Confirm wall supply is open and air flow meets minimum hospital requirements 2. Perform the Flow Test in the Service Checkout Procedure section of this manual 3. Remedy: i. Jiggle knob ii. Replace Push-To-Set™ assembly 4. See remedy D1 in this section of the manual 5. Replace or install correctly 6. Replace or install correctly
H. Inaccurate gauge reading Note: The gauge needle should return to the stop pin when no suction is being supplied.	1. Damaged gauge	1. Replace gauge
I. With the knob pushed in, unable to decrease the suction level and gauge needle does not return to zero when switched to O (OFF)	1. Blocked bleed filter and/or orifice 2. Damaged gauge 3. Cross threaded regulator module 4. Regulator module malfunction	1. Clear orifice and replace filter 2. Replace gauge 3. Install correctly 4. See “Regulator module malfunction” under the Problem column in this section of the manual
J. Limited suction in any setting	1. Selector switch not fully in CONT or INT position 2. Failed selector switch seal	1. Move fully to desired position 2. Remedy: a. Ensure Unilogic Module screws are adequately tightened b. Replace selector switch
K. Whistling/buzzing noise from inside the regulator	1. Cap-foamplug missing or deteriorated/shrunk 2. Cap-foamplug pushed too far into cap	1. Replace 2. Replace or install just flush with underside of cap
L. Gauge not aligned	1. Gauge assembled incorrectly	1. Re-assemble unit per specification
M. Longer than expected gauge bleed down time	1. Blocked or clogged gauge bleed	1. Unblock or unclog gauge bleed 2. Replace filter

7/Service - Disassembly/Assembly

7.1 Service Tools and Equipment



CAUTION: Use of lubricants other than recommended may degrade plastic or rubber components.

The following items should be on hand during any service procedure.

- Supply vacuum: 500 mm Hg/ ± 10 mmHg (67 kPa ± 1.3 kPa) & 50 LPM open air flow minimum
- Supply Vacuum Regulator with Gauge, 760 mm Hg (101.3 kPa) Full Scale.
- Low Vacuum Calibration Gauge, 225 mm Hg (30 kPa) Full Scale* (Ohio Medical P/N 6700-0353-800)
- High Vacuum Calibration Gauge, 760 mm Hg (101.3 kPa) Full Scale* (Ohio Medical P/N 6700-0352-800)
- 80 LPM Flowmeter
- Phillips Head Screwdriver, No. 2
- Flat Head Screwdriver, 1/4 inch
- Tubing Clamp
- Bubble Leak Tester
- Tweezers (Filter Remover)
- Wooden Tooth Pick (O-ring Remover)
- Pipe Cleaner
- Phillips head screwdriver No. 1
- Stop watch or vacutimer (Ohio Medical P/N 6700-0438-800)
- Open end adjustable wrench
- 10 LPM flowmeter

(*) Accuracy: $\pm 1\%$ of full scale deflection

7.2 Continuous Vacuum Regulators (All Models)

7.2.1 Disassembly



WARNING: If the Vacuum Regulator is repaired or disassembled in any manner, the Service Checkout Procedure must be performed before using the equipment on a patient.



WARNING: Clean and sterilize all suction equipment if contaminated before disassembly, to ensure service personnel are not exposed to hazardous contamination.



WARNING: When servicing a Low Vacuum Regulator, perform the Vacuum Relief Valve Adjustment and Low Vacuum Limit Setting Procedure.



CAUTION: The gauge assembly must be handled with utmost care to retain its precision. If the lens is removed, do not rest the gauge on its face.

Note: See Section 10.1 Illustrated Parts

1. Remove the four cover screws from the back of the regulator.
2. Carefully pull the cover assembly off the back body.
3. To remove the gauge assembly, grasp the assembly and pull straight out. The snap-fit lens can also be removed (if applicable) for replacement.
4. Remove actuator and PTS assembly.
5. To remove the regulator module from the cover assembly, rotate the suction control knob counterclockwise until the regulator module is free.
6. Using tweezers, remove the filter. Replace with a new filter.
7. Grasp the positive pressure safety relief valve, and pull it from the back body.
8. Remove the mounting screw from the switch plate assembly and remove the switch plate and mode switch.
9. Low models ONLY: Grasp the vacuum relief valve and pull it from the back body.

7.2.2 Assembly



CAUTION: To prevent stripping the plastic threads, place the screw in the hole and turn counterclockwise until it drops into the original thread. Tighten screw.

1. Place the positive pressure safety relief valve in position and push onto the back body.
2. Low models ONLY: Lubricate the vacuum relief valve O-ring and install it in the valve housing.
3. Lubricate switch with a thin coat of Dow 111 on the overmolded area. Place in manifold with grease side down.
4. Add detent plate making sure the fingers are on either side of the switch shaft and pointing down.
5. Place o-ring on post coming up through center of detent plate and set gauge stand over o-ring. Tighten down with 4 screws.
6. Place cylindrical white filter in corresponding cavity.
7. Screw regulator module counter-clockwise into manifold.
8. Place PTS assembly in manifold directly below regulator module.
9. Set actuator in brackets of the gauge stand and rest the loop on the top of the PTS assembly.
10. Place gear over regulator post and rest it on the actuator.
11. Place lens on gauge with single tab at the top and the two tabs at the lower portion of the gauge and set gauge into stand.
12. Place cover strip in curved slot inside case.
13. Mate the cover with the manifold. With both thumbs positioned just below the lens, press firmly to snap the lens in.
14. Install the 4 cover screws.

7.3 Suction Level Limit Setting-Low Models ONLY



WARNING: This Low Vacuum Limit Setting Procedure must be followed when repairing Low Vacuum Regulators. Failure to do this may result in suction exceeding the prescribed level.

The design of the low continuous vacuum regulator has been changed to eliminate the low vacuum limiting set screws located inside the cover behind the suction control knob. The vacuum relief valve has also been changed to limit the vacuum to the same level as the set screws did. This new vacuum relief valve has four vent holes; the old valve had two. If a new cover is used, a new vacuum relief valve must be used.

Versions with limiting screws have two means of limiting the suction level:

1. Low vacuum limiting screws in the cover; these can be set at 140 mmHg/19 kPa (± 10 mmHg/1.0 kPa).
2. Vacuum relief valve; this can be set at 165 mmHg ± 15 mmHg (22 kPa ± 2 kPa). These vacuum limit settings may be reduced to accommodate user requirements. If the vacuum limit settings are reduced, the vacuum relief valve must be set 25 mmHg ± 15 mmHg (3 kPa ± 2 kPa) higher than the vacuum limiting screws.

Versions without the limiting screws use only the relief valve to limit the suction level. The relief valve can be set at 140 mmHg ± 5 mmHg (18.7 kPa ± 0.7 kPa).

7.3.1 Low Vacuum Limiting Screws



CAUTION: When adjusting the vacuum limiting screws, be sure to adjust them to an equal height.



CAUTION: Remove the "Increase" label carefully. Press firmly in place when replacing.

1. Remove the "Increase" label and place it aside. Be careful not to damage the face or glued back of the label.
2. Adjust the two vacuum limiting screws located behind the suction control knob until they are the same height in the case. Use a 3/32" hexagonal allen wrench.
3. Connect the vacuum supply to the adapter port and occlude the fitting port.
4. Be certain that the screws remain at an equal height by adjusting both low vacuum limiting screws the same amount and in the same direction. Adjust the screws to supply a maximum vacuum of 150 mm Hg (20 kPa) and not less than 130 mm Hg (17 kPa).

7.3.2 Vacuum Relief Valve Adjustment

1. Remove the cover.
2. Connect the supply vacuum to the adapter port.
3. Turn the mode selector switch to I/ON.
4. Occlude the fitting port.
5. Slowly pull the regulator module away from the base. Note the suction level at which the relief valve opens. The relief valve should open at 165 mmHg ± 15 mmHg (22 kPa ± 2 kPa) on units with limiting setscrews and 140 mmHg ± 5 mmHg (18.7 kPa ± 0.7 kPa) for units without limiting setscrews.
6. If adjustment is required, grip the vacuum relief valve firmly with pliers and rotate the screw about 1/8 turn with a screwdriver. Repeat the previous step and check the suction level at which the valve opens.
- 7.
8. Note: Clockwise rotation will increase the suction level at which the relief valve opens. Counterclockwise rotation will decrease it.
- 9.
10. **WARNING:** Excess Loctite® may seal the steel ball to the seat. This will disable the vacuum relief valve and may allow suction to exceed the preset limit.
- 11.
12. **CAUTION:** When Loctite is used on the vacuum relief safety valve, ensure that it only contacts the metal parts. Loctite causes many plastic parts to deteriorate.
- 13.
14. Lock the adjusting screw with a drop of removable thread locker such as Loctite 242. Repeat step 5 to verify the vacuum relief valve setting.

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7.4 Regulator Module



WARNING: If repairing or replacing a regulator module on a Low Vacuum Regulator, you must perform the Suction Level Limit Setting-Low Models ONLY Procedure. Failure to do this may result in suction exceeding the prescribed level.



CAUTION: Do not lubricate any internal components of the regulator module.

CAUTION: The cap screws can strip the regulator module housing threads if they are screwed in too tight.

7.4.1 Disassembly

1. Remove timing and flow control valves by turning counterclockwise with a flat-head screwdriver.
2. Replace and/or lubricate o-rings as needed.

7.4.2 Assembly

1. Carefully insert and tighten the timing valves.
2. Press flow control valve in to engage o-ring then tighten.
3. Rotate each clockwise about 3 turns form thread engagement.

7.5 Digital Gauge

Note: Both batteries are positioned with the positive side facing up relative to the display.

7.5.1 Removal of Batteries

1. Remove digital gauge as described in 7.2.2.
2. Using a small flat head screwdriver, push batteries out at a 45° angle.

7.5.2 Inserting Batteries

1. Place negative side of battery into battery slot first (battery will be at an angle).
2. Then using a flat head screwdriver, gently push in positive battery contact while sliding battery in place.

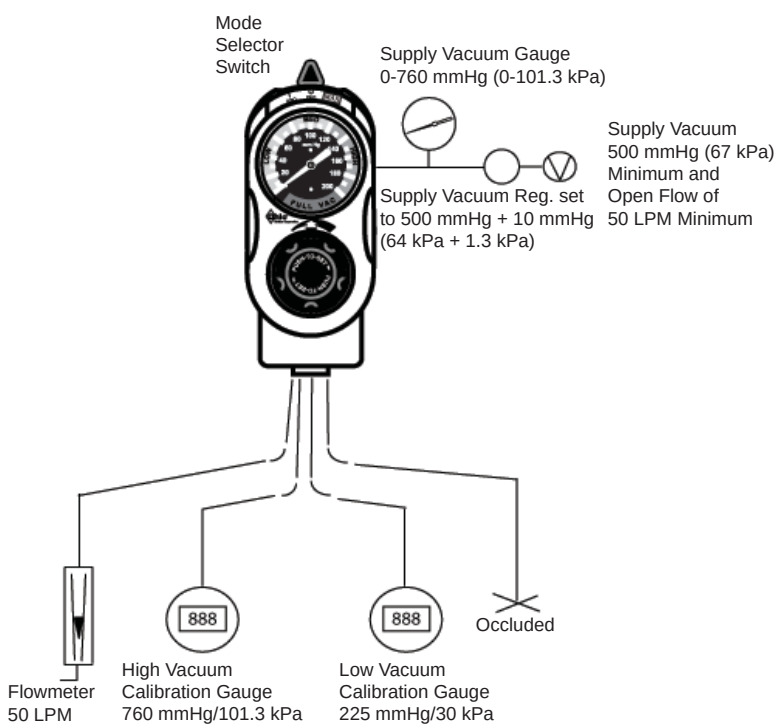


WARNING: If the Vacuum Regulator is repaired or disassembled in any manner, the Service Checkout Procedure must be performed before using the equipment on a patient.

Important: This entire Service Checkout Procedure must be performed in numerical order.

8.1 Set-up

1. Verify that there is 500 mmHg $\pm$ 10 mmHg (67 kPa $\pm$ 1.3 kPa) vacuum on the supply gauge.
2. The supply open flow must be 50 LPM minimum.
3. Connect the supply vacuum to the adapter port.



8.2 Push-To-Set™ Test

1. Connect the 10 LPM Flowmeter to the patient port.
2. Set 200 mmHg/26.6 kpa on the gauge and keep the knob pushed in.
3. Make certain leakage at the patient port connection is no more than 1 LPM.
4. While observing the flowmeter, push and rotate the knob. Leakage should be no more than 1 LPM. Replace the knob. It should fully return.

8.3 Gauge Test

Note: All Ohio Medical gauges are supplied with an accuracy of $\pm 5\%$ of full scale deflection throughout their range. The table below is provided for reference.

Note: Digital Gauges are supplied with an accuracy of $\pm 1\%$ of full range at 22°C

Note: All gauge needles should come to rest within the zero range bracket or return to the stop pin when no suction is being supplied. Gauges which do not comply may be out of calibration.

When checking gauge accuracy, be sure that the calibration gauge has an accuracy of 1% of full scale deflection or better.

8.3.1 High Vacuum Gauges ONLY

1. Connect the regulator's fitting port to the high calibration gauge with tubing.
2. Turn the mode selector switch to I (On).
3. Assure that the gauge is in agreement with the high vacuum calibration gauge within the ± 38 mmHg (5 kPa) tolerance. Recommended test points are 100, 300, and 500mm Hg.

8.3.2 Standard and Low Vacuum Gauges ONLY

1. Connect the regulator's fitting port to the low calibration gauge with tubing.
2. Turn the mode selector switch to I (On).
3. Assure that the gauge is in agreement with the low vacuum calibration gauge within the ± 10 mmHg (1.3 kPa) or the ± 8 mmHg (1.1 kPa) tolerance for standard and low gauges respectively. Recommended test points are 40, 80, and 140 mmHg.
4. For the Standard Gauge ONLY: Rotate the suction control knob fully clockwise (increase) and verify its reading is in the FULL VAC range.

8.4 Regulation Test

1. Disconnect the calibration gauge and occlude the fitting port.
2. If using a High Vacuum Regulator, set its gauge to 300 mmHg (40 kPa). If using a Low or Standard Vacuum Regulator, set its gauge to 100 mmHg/14 kPa.
3. Open and close the fitting port several times.
4. With the fitting port occluded, the gauge should return to the setting listed in step 2 within a tolerance of:

± 38 mmHg (5 kPa) for high vacuum gauge

or

± 10 mmHg (1.3 kPa) for the standard vacuum gauges

or

± 8 mmHg (1.1 kPa) for the low vacuum gauge.

8.5 Low Vacuum Regulators ONLY

1. Occlude the fitting port.
2. Rotate the suction control knob fully clockwise (increase).
3. Verify that the suction delivered does not exceed 150 mm Hg (20 kPa) or the maximum suction requested by the clinician.

Note: For setting the Suction level limit, refer to Suction Level Limit Setting-Low Models ONLY.

8.6 Bleed Test

1. Occlude the fitting port and set the vacuum level to 100 mm Hg (14 kPa).
2. Turn the selector switch to O (Off) and observe the gauge needle. It must return to the zero range bracket or stop pin within 10 seconds.

8.7 Leak Test - Supply Side

1. Connect the supply vacuum tubing to port "A" of the Bubble Leak Tester.
2. Connect port "B" of the Bubble Leak Tester to the regulator adapter port.
3. Turn the mode selector switch to O (Off). Allow the fitting port to be open to air.
4. Wait 20 seconds. No More than 6 bubbles should appear in the next ten seconds.

Important: Prior to venting port "A" of the Bubble Leak Tester to atmosphere (i.e. turning the supply regulator off), ensure the tubing from port "B" has been disconnected from the adapter port of the vacuum regulator.

8.8 Leak Test - Patient Side

1. Connect the supply vacuum tubing to the regulator adapter port.
2. Connect the regulator fitting port to port "A" of the Bubble Leak Tester with tubing. Allow port "B" of the Bubble Leak Tester to be open to air.
3. Rotate the suction control knob a minimum of one full turn clockwise (increase). No bubbles should appear in the next ten seconds.
4. Rotate the suction control knob fully counterclockwise (decrease).
5. Turn the mode selector switch to I (On). No bubbles should appear in the next ten seconds.

9/Maintenance

9.1 General Maintenance of Suction Equipment

 **WARNING:** The Pre-Use Checkout Procedure must be performed before using this equipment on each patient. If the regulator fails any part of the Pre-Use Checkout Procedure, it must be removed from service and repaired by qualified service personnel.

 **WARNING:** Clean and sterilize all suction equipment if contaminated before disassembly, to ensure service personnel are not exposed to hazardous contamination.

Continuous Vacuum Regulators should be kept in use or used on a rotating basis. Unused equipment may tend to deteriorate.

Maintenance of the vacuum piping system is as important as maintenance of the suction equipment. The use of Collection Bottles with reliable shut-off valves, Overflow Safety Trap assemblies and disposable suction filters will protect the regulator and piping system. The flow rate at the wall outlet should be checked on a yearly basis and suitable cleaning of the outlets should be performed. The flow rate measurement should meet local standards.

Routine maintenance and inspection are important to the performance of suction equipment. The following is a recommended list for care of suction equipment after each patient use.

1. Perform a thorough cleaning by washing all bottles, tubing, metal connectors, etc, and removing all residue.
2. Wipe all exterior surfaces with a solution of water and mild detergent.
3. Perform a careful visual inspection.
4. Check that the High Flow Disposable Suction Filter is clean and in good condition.
5. Check that all tubing is in good condition and connected securely to the correct ports.
6. Check the floats in the Overflow Safety Trap and Collection Bottle for correct operation.
7. Perform the Pre-Use Checkout Procedure.

9.2 Recommended Maintenance Schedule

Ohio Medical vacuum regulators function for decades. They are proven to provide trouble-free service with minimum care.

We recommend the following to determine the maintenance schedule appropriate for each facility:

1. Periodically (as required, but no less than annually) inspect the overall condition of the vacuum regulator. Test gauge accuracy (section 8.6 Gauge Test) and perform the Pre-Use Checkout Procedure (section 4.4). If the regulator does not pass, refer to Troubleshooting (Section 6).
2. Determine a maintenance schedule based on data from your periodic inspections. Follow the guidelines below.

9.2 Recommended Maintenance Schedule

Item	Minimum Frequency	Comments
Service Checkout Procedure	Every 24 months or as required	If the regulator does not pass, refer to Troubleshooting (Section 6). Repair as needed
Elastomeric parts, O-rings, gaskets, diaphragms, internal filters	As required	Cleaning, lubrication and replacement interval depends on hours of usage and environmental conditions. Replace, lubricate, and repair as needed

9.3 Repair Policy

 **WARNING:** Clean and sterilize all suction equipment before shipment or service to ensure transportation personnel and/or service personnel are not exposed to any hazardous contamination.

 **CAUTION:** Do not steam autoclave or liquid sterilize the Continuous Vacuum Regulator. Severe impairment to the operation of the regulator will result. The only acceptable method of sterilization is with gas (ethylene oxide).

 **CAUTION:** Only competent individuals trained in the repair of this equipment should attempt to service it.

Do not use malfunctioning equipment. Make all necessary repairs. Have the equipment repaired by qualified service personnel or by Ohio Medical. Parts listed in the service manual for this product may be repaired or replaced by a competent, trained person who has experience in repairing devices of this nature. After repair, perform the Service Checkout Procedure to ensure that it is functioning properly, and complies with the published specifications.

9.4 Technical Assistance

If technical assistance is required, contact Ohio Medical technical support or field operations listed on the back cover.

9.5 Return Instructions

1. Call 866-549-6446 for a returned goods authorization.
2. Clean and sterilize the Vacuum Regulator.
3. Package the Vacuum Regulator securely for protection; preferably in the original container.
4. Include a letter describing in detail any difficulties experienced with the Vacuum Regulator. Include the person, title, and telephone number to contact for functional questions.
5. Ohio Medical now offers a ten year warranty on vacuum regulators sold on or after July 1, 2005. If the vacuum regulator was purchased on or after July 1, 2005 and is less than ten years old or if the vacuum regulator is covered under the previous warranty and is less than five years old, include the warranty information that came with the device and a copy of the invoice.
6. Include a purchase order to cover repair of a regulator not under warranty.
7. Ship the Vacuum Regulator prepaid. Write your return address and billing address information on the package or letter that comes with the package.

For all Repairs Contact your nearest Ohio Medical office or authorized Ohio Medical Distributor.

9/Maintenance

9.6 Warranty

This Product is sold by Ohio Medical under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this Product directly from Ohio Medical or Ohio Medical's

Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for purpose of resale. For a period of One hundred and twenty (120) months from the date of original delivery to Buyer or to Buyer's order, but in no event for a period of more than two years from the date of original delivery by Ohio Medical to an Ohio Medical Authorized Dealer, this Product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the Product contained in this operation manual and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided. This same warranty is made for a period of thirty (30) days with respect to the expendable parts. The foregoing warranties shall not apply if the Product has been repaired other than by Ohio Medical or in accordance with written instructions provided by Ohio Medical, or altered by anyone other than Ohio Medical, or if the Product has been subject to abuse, misuse, negligence, or accident.

Ohio Medical's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at Ohio Medical's option, a Product, which is telephonically reported to the nearest Ohio Medical Regional Service Office and which, if so advised by Ohio Medical, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty, to the designated Ohio Medical Service Office during normal business hours, transportation charges prepaid, and which, upon Ohio Medical's examination, is found not to conform with the above warranties. Ohio Medical shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. Ohio Medical makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

9.7 Installation Procedure for Adapters/Probes and Fittings



CAUTION: Do not use any ⁴Loctite® products to seal the threads (or product which contain Methacrylate Ester as an active ingredient).

All adapters/probes and fittings should be installed properly to prevent leaks and to support the equipment when mounted. Both vacuum regulator ports are 1/8-27 NPT tapered pipe threads. It is important to note that adapters/probes and fittings seal on the thread and may have threads exposed after they have been tightened properly.

Prior to installing the adapter/probe or fitting, wrap the thread with PTFE tape or apply Dow® 111, ³Ball Vac-Kote (37951M) or equivalent.

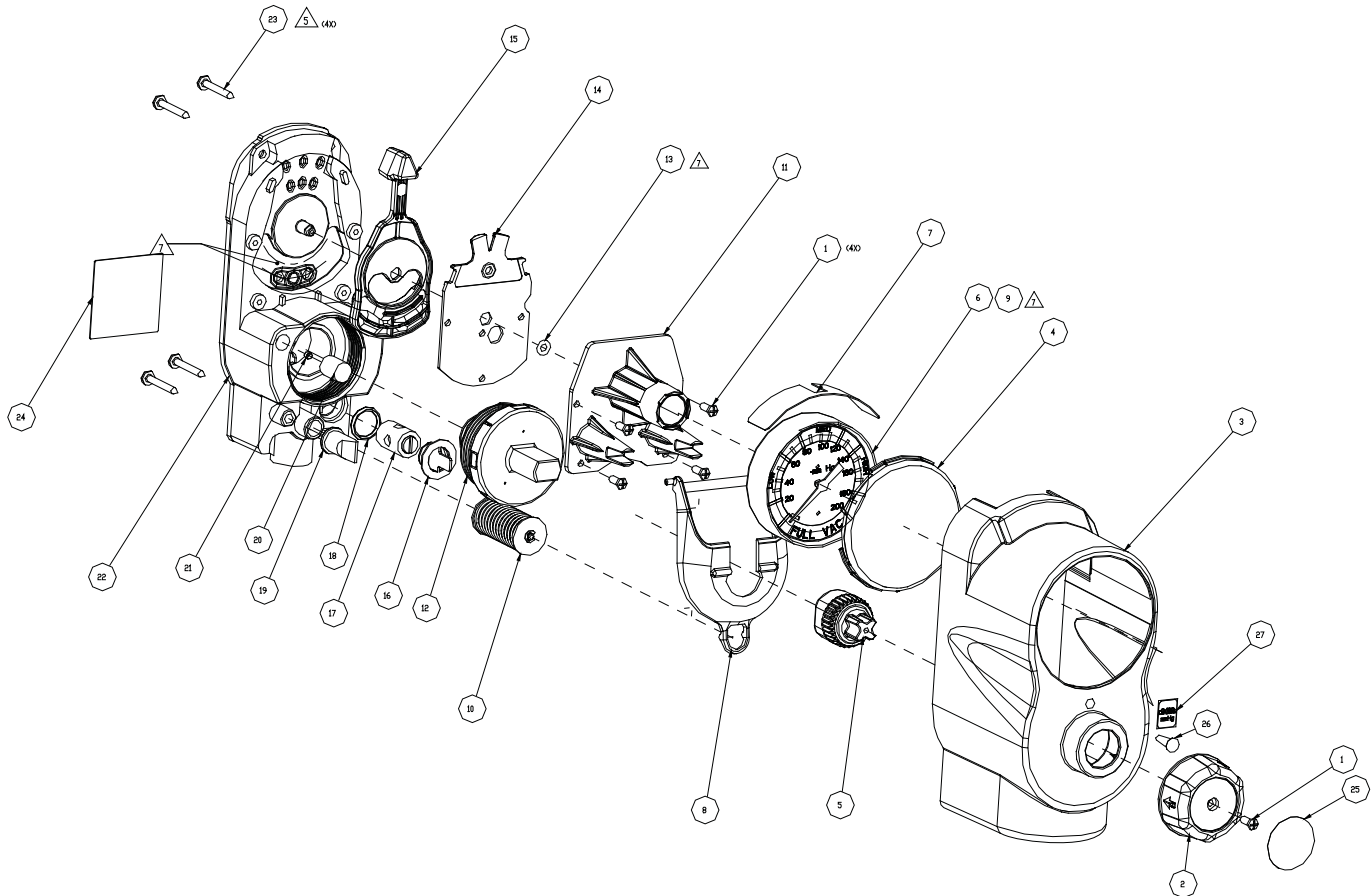
The torque range for installing adapters/probes and fittings is 4.0 ft-lb (5.4 N-m) minimum to 10.0 ft-lb (13.6 N-m) maximum. Adapters/probes and fittings which are not keyed for specific orientation, should be torqued to approximately 6.0 ft-lb (8.1 N-m).

Adapters/probes and fittings that are keyed to specific orientation, must be torqued initially to 4.0 ft-lbs (5.4 N-m). Additional torque is applied only until orientation is correct.

³ Ball Vac-Kote is a registered trademark of the Ball Aerospace Systems Division.

⁴ Loctite is a registered trademark of Loctite Corporation.

10.1 Illustrated Parts



Item	Part Number	Description	Qty
1	6700-0078-400	Screw, PHH PNH, 4-20 Plastite	5
2	8700-0017-500	Knob	1
3	See Table	Case, Regulator	1
4	8700-0041-500	Gauge Lens	1
5	8700-0021-500	Drive Gear, Occlude-To-Set	1
6	See table below	Gauge, Vacuum	1
7	8700-0038-500	Cover Strip, Switch	1
8	8700-0015-500	Actuator, Occlude-To-Set	1
9	6700-0175-500	O-Ring, 2-013 Nitrile	1
10	8700-0002-700	OTS Assembly	1
11	8700-0043-500	Support Bracket, Actuator	1
12	8700-0001-700	Assembly, Reg Mod	1
13	0210-0525-300	O-Ring, 9.32 OD x 5.32 IS x 1/16 W	1
14	8700-0040-500	Plate, Detent	1

Item	Part Number	Description	Qty
15	8700-0016-500	Selector Switch, Overmolded	1
16	See table below	Plug, Pull Tab	1
17	See table below	Vacuum Relief Assembly	1
18	See table below	O-Ring, 2-014, Nitrile, Buna-N	1
19	6700-0115-400	Relief Valve, Positive Pressure	1
20	0206-5159-300	Plug, Filter	1
21	6700-0121-400	Orifice, Continuous Vacuum Regulator	1
22	8700-0009-700	Manifold Assembly	1
23	6700-0151-400	Screw, Self Tap, #6 Pan Head	4
24	8700-0016-100	Serial Number Label	1
25	8700-0005-100	Knob, Label	1
26	8700-0056-500	Plug	1
27	See table below	Label	1

Model #	Item 3 Case, Regulator	Item 16 Plug, Pull Tab	Item 17 Vacuum Relief Assembly	Item 18 O-Ring, 2-014, Nitrile, Buna-N	Item 27 Label
1224	8700-0012-500	8700-0039-500	N/A	N/A/	N/A
1225	8700-0022-500	8700-0039-500	N/A	N/A	N/A
1226	8700-0012-500	8700-0039-500	N/A	N/A	N/A
1227	8700-0022-500	N/A	6700-0045-700	6700-0135-500	8700-0036-101
1231	8700-0053-500	N/A	6700-0045-700	6700-0135-500	8700-0036-102
1234	8700-0053-500	N/A	6700-0045-700	6700-0135-500	N/A
1330	8700-0022-500	8700-0039-500	N/A	N/A/	N/A

Item 6 Vacuum Gauge, Analog		Item 6 Vacuum Gauge, Digital	
Range	P/N	Range	P/N
0-200 mmHg	8700-0002-400	0-160 mmHg	VR-DGP-160MM
0-760 mmHg	8700-0022-400	0-200 mmHg	VR-DGP-200MM
0-160 mmHg	8700-0024-400	0-650 mmHg	VR-DGP-760MM
		Replacement Battery	VR-DGP-BAT



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